## 1005-42 Recanalization of Long Superficial Femoral Artery Occlusions by a Transpopliteal Approach: Acute and 12- Month Results

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**Objective**: Although crossover recanalization of chronic superficial femoral artery (SFA) has shown higher technical success rates than antegrade recanalization, in long chronic SFA occlusions there is still a considerable technical failure rate due to inability to cross the occlusion.
**Methods**: We analyzed the acute and 12 month results of 103 patients who underwent transpopliteal recanalization of long chronic SFA occlusions (mean length 14.8 cm). In 82 patients the popliteal approach was used as a salvage technique after failure to pass the occlusion using an antgrade way due to subintimal passage. In the remaining 21 cases the transpopliteal route was used as the primary approach to cross flush occlusions of the SFA without patent proximal stump of the vessel. Puncture of the popliteal artery was performed using fluorescopic control and road mapping after contrast injection through an ipsilateral or contralateral F4 femoral access. In all cases the distal third of the SFA as well as the popliteal artery were patent allowing placement of a 6 French introducer sheath. Retrograde recanalization of the SFA occlusion was performed using hydrophilic guide wires and Excimer laser assistance followed by adjunctive balloon angioplasty (diameter 5-6 mm).
**Results**: A technical successful recanalization could be achieved in 89 of 103 cases (86.4%). There were no major procedure related adverse events. Puncture site complications occured in 11 cases (10.7%). There were 3 false aneurysms (2.9%), 6 hematomas (5.8%) and 2 cases of thrombotic occlusion of the popliteal artery / tibioperoneal trunk (1.9%). In both cases we were able to mechanically recanalize the thrombotic occlusion. Primary and secondary patency rates after 12 months as assessed by colour-coded ultrasound were 54.4% and 73.8%, respectively.
**Conclusion**: The transpopliteal approach is an alternative effective technique to recanalize long SFA occlusions, which could not be crossed by standard techniques.

## 1005-43 The Foundation for Advanced Medical Education Renal and Iliac Artery Stent Training Program

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Background: Cardiovascular medicine continues to evolve rapidly as new approaches and new technology are explored, developed, and incorporated into practice.Physicians, particularly cardiologists, are expected to practice in the most effective manner by developing and disseminating new knowledge and new skills. To assess the effectiveness of introducing new procedures to physicians already in practice, a group of interventional cardiologists and vascular surgeons undertook an initiative to teach their peers to stent renal and iliac arteries.
Methods: A comprehensive program was devised, including a didactic portion (via distance learning), an animal practicum, a simulation, and a preceptor/preceptee segment, followed by an assessment by the participants. The program ascribed to the guidelines of the American College of Cardiology for procedural training.
Results: Six preceptors and 25 preceptees undertook and later evaluated the program. Preceptors were more critical of the overall initiative than preceptees, and surgeons were more critical than cardiologists. Preceptors rated the skills of the cardiologists higher than those of the surgeons. Preceptees gave the most enthusiastic feedback about the animal practicum and provided helpful suggestions to improve the technical aspects of the simulation.
Conclusion: Training physicians with different skill sets and cognitive processes is challenging, but overcoming the challenges is vital to assure that cardiovascular medicine continues to move forward by incorporating new procedures that will improve patient care.

## 1005-44 Vascular Brachytherapy With $^{192}$Iridium After Femoropopliteal Stenting in High-Risk Patients: Results From the Vienna-5 Trial

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**BACKGROUND:** To evaluate the efficacy of endovascular brachytherapy (EBT) for the prevention of restenosis after femoropopliteal stenting in high-risk patients.
**MATERIALS AND METHODS:** A total of 88 patients with femoropopliteal lesions (mean treatment length 16.8 ± 7.3 cm) were included into the trial. Patients underwent PTA and stent implantation and were randomized in a double blinded fashion to receive either gamma-EBT with an $^{192}$Iridium source or treatment with non-radioactive seeds. A dose of 14 Gy was prescribed at 2mm into the arterial wall (target depth = vessel radius + 2mm). The primary endpoint was angiographic binary restenosis >50% at 6 months.
**RESULTS:** Revascularization and EBT were successfully accomplished in all patients. The overall 6-month recurrence rate was 34.8% in the Stent- vs. 33.3% in the Stent plus EBT group, (p=0.89). Nine (10.2%) patients developed early re-occlusion of the stented segment (2 patients [4.3%] in the Stent- and 7 [16.7%] in the Stent + EBT group), among those 3 patients in the EBT group within the first 24 hours after intervention. Late thrombotic occlusion (LTO >30 days) was observed in 3 patients (7.1%) in the Stent plus EBT group.
**CONCLUSION:** ETB does not improve 6-months patency after femoropopliteal stenting in high risk patients, due to a high incidence of early and late thrombotic occlusion.

## 1005-45 Dose Response of Sirolimus-Eluting SMART$^{TM}$ Stents in Porcine Iliac Arteries and Relationship to Arterial Tissue Sirolimus Levels

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**Background:** The dose-response of peripheral arteries to sirolimus delivered from sirolimus-eluting stents has not been established. This study was performed to evaluate several doses of sirolimus-eluting SMART stents and to correlate the vascular response to tissue sirolimus levels. **Methods:** To assess efficacy, 8x40 mm SMART stents coated with 50, 150, 500 & 1500μg/stent sirolimus or control metal or polymer-coated SMART stents were implanted in the iliac arteries of 36 Yucatan miniswine. After a 30, 90 or 180 day recovery period, the iliac arteries were removed and prepared for histomorphometric analysis. All doses were studied at 30 days but only the 500μg and 1500 μg/stent doses were studied at 90 and 180 days. Arterial sirolimus was determined by implanting the same four doses of drug eluting stents in the iliac arteries of an additional 45 miniswine and removing the arteries after either 1, 3, 8 and 30 days; the 500 & 1500μg/stent doses were continued for 90 days. **Results:** At 30 days, significant ($p<0.05$) reductions in neointimal area were noted in the 150μg, 500μg and 1500μg/stent groups but not in the 50μg/stent group (see Table). Peak tissue levels ranged from 0.6 to 68 ng/mg. However reduction in neointimal area was not observed with peak tissue levels below 1 ng/mg. **Conclusion:** This dose-response revealed safety at all sirolimus doses and maximum benefit at the 500μg dose. The lack of efficacy at 50μg establishes for the first time apparent minimal tissue levels needed for pharmacological activity.

Dose Response Efficacy at Day 30 and Arterial Tissue Sirolimus Levels

| Stent/ Dose | Initimal Area ($mm^2$) | Intima/ Media Ratio | % Area Occlusion | Initimal Thickness (μm) | Tissue Level Day 1 (ng/ mg) | Tissue Level Day 3 (ng/ mg) |
|---|---|---|---|---|---|---|
| Bare Metal | 7.11±2.91 | 2.90±0.99 | 21.16±5.60 | 417.3±123.5 | -- | -- |
| Polymer Control | 9.66±4.95 | 3.51±2.96 | 28.66±8.59 | 567.6±220.8 | -- | -- |
| 50 μg | 7.60±4.46 | 3.36±2.67 | 22.15±10.18 | 447.3±230.4 | 0.577±0.164 | 0.338±0.117 |
| 150 μg | 4.31±0.82* | 2.39±0.49 | 15.98±2.39 | 296.6±38.3 | 2.32±1.12 | 1.48±1.54 |
| 500 μg | 3.88±0.86* | 1.70±0.28 | 15.33±3.10 | 281.4±49.1 | 5.93±1.28 | 4.21±0.856 |
| 1500 μg | 5.44±4.02* | 2.06±0.71 | 16.75±7.65 | 336.1±176.2 | 36.56±12.31 | 67.94±31.37 |
| | *= P < 0.05; ANOVA/ Dunnetts Test | | | | | |

## 1005-46 Percutaneous Peripheral Intervention Is Associated With Sustained Improvement in Health-Related Quality of Life

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**Background:** There is a paucity of data substantiating benefit among patients undergoing peripheral percutaneous intervention (PPI). The Peripheral Arterial Questionnaire (PAQ) is a recently developed and validated 20-item self-administered Likert-style instrument that assess functional and quality of life (QOL) limitations specifically due to peripheral arterial disease (PAD).
**Methods:** QOL assessments utilizing the PAQ were performed on 216 consecutive patients undergoing lower extremity PPI for treatment of claudication prior to and 1,3,6, and 12 months after PPI.
**Results**: Of the 216 patients undergoing PPI, 130 (63%) were male, 79 (38%) had diabetes, 129 (64%) had dyslipidemia, 134 (67%) had hypertension, 96 (46%) were current smokers, and the mean age was 68 ± 12 years. Angiographically, 58(28%) of patients had bilateral disease, 104 (45%) had multilevel disease, and 46 (22%) had total occlusions. Following PPI, there was a significant and sustained improvement in health related QOL ($p<0.001$ for trend) [fig 1]. Variability in the magnitude of benefit 1 month following PPI was observed (inset).
**Conclusions:** These data suggest that PPI for the treatment of lifestyle-limiting claudication is effective and associated with a significant and sustained improvement in QOL. Further study is needed to understand the patient and procedural characteristics associated with the greatest benefit from PPI.